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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/694,664 | 10/29/2003 | William Gartner | 340885.90013 | 4235 |

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| EXAMINER |
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SUHOL, DMITRY

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| ART UNIT | PAPER NUMBER |
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3712

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/694,664 | Applicant(s) GARTNER ET AL. | |
| | Examiner Dmitry Suhol | Art Unit 3712 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/29/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Recent progress in the development of a clinically useful microencapsulated olfactory function test" by Doty et al (here from referred to as RPDOT) in view of Cotman (WO 89/00398) and Ladd et al '139. RPDOT discloses an olfactory test for self-administered screening of neurological disease containing most of the elements of the claims including, a plurality of odor containing sources as required by claim 1 (page 5, last paragraph), each odor-containing source containing a familiar odor as required by claim 1 (page 6, last sentence in second paragraph), a plurality of labels located adjacent to each of the odor-containing sources and providing choices of possible identity of the odor-containing source as required by claim 1 (page 6, first paragraph). Four labels being provided for each odor-containing source, as required by claim 5, are described on page 6, first paragraph. A plurality of labels for each odor-containing source being distinctly different from each other, as required by claim 6, described in the first paragraph on page 6. A plurality of odor-containing sources being distinctly different

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from each other, as required by claim 7, is described on page 5 in the last paragraph and on page 6 in the second paragraph.

RPDOT lacks an explicit teaching of an removably covered answer key as required by claim 1, a first, second (as required by claim 3) and third instruction for self-administering, self-scoring, and self-interpreting the olfactory test as required by claim 1, an odor containing source having a unique distinguishing feature, as required by claims 10, a neurological disease being Alzheimer's as required by claim 11. a first sheet with an instruction for a medical professional as required by claim 12. However, Ladd discloses a booklet having an olfactory test thereon (stimulus page 30) which teaches incorporating a removably covered answer key (display page 28) where it is considered that since the display page (28) would be covered by a variety of other pages while the user looks at the question page (30) then it (e.g. display page 28) is removably covered. Cotman discloses a kit for olfactory testing which teaches providing instructions for self-scoring the olfactory test (page 8, lines 1-4) in order to diagnose a possible onset of Alzheimer's disease (as required by claim 11) (page 8, lines 5-6). Cotman further teaches an odor containing source having a unique distinguishing feature (figure 2, element 1). Therefore it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to provide a removably covered answer key and instructions with the test of RPDOT for the purpose of positive identification and interpretation of the results of the test, especially since the booklet of RPDOT is concerned with self-administration of the olfactory test (see RPDOT page 5, second paragraph, first sentence). It would have been further obvious to provide a unique

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distinguishing feature on the odor source for the purpose of clear identification of the location of the source.

Regarding the specifics of the first, second and third instructions as required by claims 1, 2, 3 and 12, it would have been obvious to provide a first, second and third instruction with the specifics of claims 1, 2, 3 and 12 since it would only depend on the intended use of the assembly and the desired information to be displayed. Further, it has been held that when the claimed printed matter is not functionally related to the substrate it will not distinguish the invention from the prior art in terms of patentability. *In re Gulack*, 217 USPQ 401, (CAFC 1983). The fact that the content of the printed matter placed on the substrate may render the device more convenient by providing an individual with a specific type of instruction does not alter the functional relationship. Mere support by the substrate for the printed matter is not the kind of functional relationship necessary for patentability. Thus, there is no novel and unobvious functional relationship between the printed matter (e.g. instructions) and the substrate (e.g. olfactory test) which is required for patentability.

Regarding the specific layout as required by claims 8 and 9, the examiner takes official notice that such an arrangement of labels and odor-containing sources is utilized in the UPSIT described in the RPDOT reference.

An instrument for recording the possible identity of an odor-containing source (as required by claim 13) would have been obvious since examiner takes official notice of such devices being well known in the art (i.e. a pen, and a piece of plastic).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Recent progress in the development of a clinically useful microencapsulated olfactory function test" by Doty et al (here from referred to as RPDOT) in view of Cotman (WO 89/00398) and Rugland et al '689. Although RPDOT and Cotman disclose most of the elements, as stated above, the references fail to teach a removably covered answer key (as required by claim 1) utilizing a sealed cover sheet (as required by claim 4).

However, Gugland discloses a multiple choice test which teaches that it is known to provide a removably covered answer key (12) utilizing a sealed cover sheet (figure 1). Therefore it would have been obvious to incorporate a removably covered answer key utilizing a sealed cover sheet in the device of RPDOT, as modified by Cotman, for the purpose of preventing the examinee from gaining access to the scoring sheet as the RPDOT directed to a self administered test.

Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Recent progress in the development of a clinically useful microencapsulated olfactory function test" by Doty et al (here from referred to as RPDOT) in view of Cotman (WO 89/00398), Ladd et al '139 and Buschke '629. RPDOT, as modified by Cotman and Ladd, discloses most of the elements of the claims, as stated above, but for the steps of self-administering, self-scoring and self-interpreting the test without the assistance from a medical professional as required by claim 14. However, Buschke discloses a medical test device for the determination of Alzheimer's which teaches that it is known to provide an at home self-test which allows for self-administration, self-scoring and self-

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interpreting the results of the test without the help of a medical professional (col. 2, lines 37-39 and col. 5, lines 28-33). Therefore it would have been obvious to incorporate the steps of self-administering, self-scoring and self-interpreting with the test of RPDOT without the assistance from a medical professional for the purpose of providing a reliable, rapid test for self-testing at home or elsewhere, especially since RPDOT clearly teaches that their test is self-administered (RPDOT, page 5, second paragraph).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dmitry Suhol whose telephone number is 703-305-0085. The examiner can normally be reached on Mon - Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks can be reached on 703-308-1745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'D. Banks', with a long horizontal line extending to the right.

DERRIS H. BANKS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700